



## United States Patent Application

## SUBSTITUTE DECLARATION UNDER 37 C.F.R. § 1.63

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **STERILE DEVICE AND METHOD FOR PRODUCING SAME**

The specification of which

a. ☐ is attached hereto.

b. ☒ was filed on December 28, 2001 as Application Serial No. 10/034,505, which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (attached hereto).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

- a. ☒ no such applications have been filed.  
b. ☐ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
ALL FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. PARENT APPLICATION NUMBER	PCT PARENT APPLICATION NUMBER	PARENT FILING DATE	PARENT PATENT NUMBER


I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)
60/335,978	23, October, 2001

Please direct all correspondence in this case to Ted R. Rittmaster, Esq. at the address indicated below:

Ted R. Rittmaster  
Foley & Lardner  
2029 Century Park East - Suite 3500  
Los Angeles, CA 90067-3021

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2	<b>Full Name Of Inventor</b>	<b>Family Name</b> Swanson	<b>First Given Name</b> Aaron	<b>Second Given Name</b> J.
0	<b>Residence &amp; Citizenship</b>	<b>City</b> Los Angeles	<b>State or Foreign Country</b> California	<b>Country of Citizenship</b> US
1	<b>Post Office Address</b>	<b>Post Office Address</b> 6701 West 87th Street	<b>City</b> Los Angeles	<b>State &amp; Zip Code/Country</b> California 90045/USA
<b>Signature of Inventor 201:</b>				<b>Date:</b>
2	<b>Full Name Of Inventor</b>	<b>Family Name</b> Reynolds	<b>First Given Name</b> Jennifer	<b>Second Given Name</b> M.
0	<b>Residence &amp; Citizenship</b>	<b>City</b> Simi Valley	<b>State or Foreign Country</b> California	<b>Country of Citizenship</b> US
2	<b>Post Office Address</b>	<b>Post Office Address</b> 1243 Fourth Street	<b>City</b> Simi Valley	<b>State &amp; Zip Code/Country</b> California 93065/USA
<b>Signature of Inventor 202:</b>				<b>Date:</b>
2	<b>Full Name Of Inventor</b>	<b>Family Name</b> Shah	<b>First Given Name</b> Rajiv	<b>Second Given Name</b> --
0	<b>Residence &amp; Citizenship</b>	<b>City</b> Rancho Palos Verdes	<b>State or Foreign Country</b> California	<b>Country of Citizenship</b> US
3	<b>Post Office Address</b>	<b>Post Office Address</b> 28003 Lobbrook	<b>City</b> Rancho Palos Verdes	<b>State &amp; Zip Code/Country</b> California 90275/USA
<b>Signature of Inventor 203:</b> 				<b>Date:</b> 10/15/03

**§ 1.56 Duty to disclose information material to patentability.**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;  
or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application:

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant: Aaron Swanson et al.

Title: STERILE DEVICE AND METHOD  
FOR PRODUCING SAME

Appl. No.: 10/034,505

Filing Date: December 28, 2001

Examiner: Unassigned

Art Unit: 1744

Atty. Dkt. No. 047711-0294

**SUBSTITUTE PROPERTY RIGHTS DECLARATION**

We, Aaron Swanson, Jennifer M. Reynolds and Rajiv Shah, citizens of the United States of America, residing at 6701 West 87<sup>th</sup> Street, Los Angeles, CA 90045; 1243 Fourth Street, Simi Valley, CA 93065; and 28003 Lobbrook, Rancho Palos Verdes, CA 90275, respectively, declare:

That we made and conceived the invention described and claimed in patent application: Serial Number 10/034,505, filed in the United States of American on December 28, 2001, titled STERILE DEVICE AND METHOD FOR PRODUCING SAME.

*(Check and complete either I or II below)*

*(Check III and/or IV below as appropriate)*

☒ I. *(For Inventors Employed by an Organization)* That we made and conceived this invention while employed by Medical Research Group; that the invention is related to the work we are employed to perform and was made within the scope of our employment duties; that the invention was made during working hours and with the use of facilities, equipment, materials, funds, information and services of Medical Research Group.

Other relevant facts are that the invention relates to the sterilization of medical devices and is not related in any way to nuclear material or atomic energy. The invention was designed and developed pursuant to Medical Research Group business objectives, which have no fiscal or other relationship to the DOE or NASA.

—OR—

☐ II. *(For Self-Employed Inventors)* That I (we) made and conceived this invention on my (our) own time using only my (our) own facilities, equipment, materials, funds, information and services. Other relevant facts are

That to the best of our knowledge and belief:

☒ III. The invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration or the Department of Energy.

—AND/OR—

☒ IV. The invention was not made (conceived or first actually reduced to practice) under nor is there any relationship of the invention to the performance of any work under any contract of the National Aeronautics and Space Administration.

The undersigned inventor(s) declare further that all statements made herein of his or her (their) own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Inventor's name: Aaron J. Swanson

Inventor's Signature: \_\_\_\_\_

Post Office Address: 6701 West 87<sup>th</sup> Street, Los Angeles, CA 90045

Date: \_\_\_\_\_

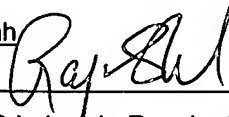
Inventor's name: Jennifer M. Reynolds

Inventor's Signature: \_\_\_\_\_

Post Office Address: 1243 Fourth Street, Simi Valley, CA 93065

Date: \_\_\_\_\_

Inventor's name: Rajiv Shah

Inventor's Signature:  10/15/03

Post Office Address: 28003 Lobbrook, Rancho Palos Verdes, CA 90275

Date: \_\_\_\_\_